

Study

(MIABIS 2.0 Core, <https://doi.org/10.1089/bio.2015.0070>)

Study represents a set of samples brought together in the context of a research study.

REGULATION (EU) No 536/2014

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

“(1) ‘Clinical study’ means any investigation in relation to humans intended:

- (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;
 - (b) to identify any adverse reactions to one or more medicinal products; or
 - (c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products;
- with the objective of ascertaining the safety and/or efficacy of those medicinal products;

(2) ‘Clinical trial’ means a clinical study which fulfils any of the following conditions:

- (a) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned;
- (b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or
- (c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.

[...]

(4) ‘Non-interventional study’ means a clinical study other than a clinical trial; ”